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18M1/1030

EXAMINER	
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ART UNIT	PAPER NUMBER
1806	10

DATE MAILED: 10/30/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

## Office Action Summary

Application No. <b>08/417,174</b>	Applicant(s) <b>Kawakami et al</b>
Examiner <b>Sheela J. Huff</b>	Group Art Unit <b>1806</b>



Responsive to communication(s) filed on Aug 6, 1996

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-38 is/are pending in the application.

Of the above, claim(s) 1-14, 27-31(MART-1) and 32-38 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 15-18, 22-26, 27-31 (gp100) is/are rejected.

Claim(s) 19-21 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

1. This application is a CIP of 08/231565.

### ***Election/Restriction***

2. Applicant's election with traverse of Group II, claims 15-26, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Groups I, II and IV are assigned to class 530 and therefore searching Groups II-IV together does not result in an unduly burdensome search. Applicant further argues that the proteins are produced by the nucleic acid sequences of Group III. This is not found persuasive because the subclasses of Groups II and I in Class 530 are different and peptides are not antibodies. The proteins gp100 and MART-1 are structurally different proteins.

The requirement is still deemed proper and is therefore made FINAL.

3. The election requirement between gp100 and MART-1 of claims 27-31 remains.

Since applicant elected group II directed to gp100, claims 27-31 will be examined as they are directed to gp100.

Therefore, claims 15-26 and claims 27-31 (gp100) are currently under consideration.

Claims 1-14, 27-31 (MART-1) and 32-38 are withdrawn from consideration.

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***Information Disclosure Statement***

4. The IDS filed on 2/23/96 has been considered. A copy of the initialed PTO-1449 is enclosed.

***Claim Objections***

5. Claims 19-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to a previous claim in the alternative. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

*SJH  
10/26/96*

Claims 15-18 and 22-~~29~~<sup>31</sup> are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for gp100, the peptides of claims 17 and 18, the peptides of claim 22 having naturally occurring amino acids does not reasonably provide enablement for peptides "derived from gp100", peptides of claim 22 having non-naturally occurring amino acids and the use thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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In claim 15, applicant is claiming a peptide "derived from" gp100. The sequence of gp100 has 661 amino acids and a peptide "derived from" said sequence could be as small as a dimer or as long as 660 amino acids and would have amino acid substitutions. Thus, the claim reads on thousands of peptides. There is no guidance in the specification as to the length of the peptides, the substitutions that could be tolerated by the peptides or even what the function of the peptides. Is the peptide simply supposed to immunogenic or can all of the peptides be used in treatment of melanomas?

With respect to claim 22, applicant is claiming "any amino acid". This reads on naturally and non-naturally occurring amino acids. It is well known that D-amino acids are very different from L-amino acids and also that single amino acid change in a small peptide can drastically alter the peptide's conformation, polarity, etc and thereby effecting the peptide's function.

Thus, there is no guidance in the specification to enable the scope of the peptides and therefore undue experimentation would be required by one skilled in the art to make and use the claimed invention.

*✓* Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of melanomas does not reasonably provide enablement for "prevention and "vaccines". The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 30 applicant is claiming a method of "prevention". In claim 31 applicant is claiming a "vaccine". The examples only enable treating. "Prevention" means that the peptides are administered prior to the onset of the disease and that the disease does not occur. "Vaccine" means the same thing as "prevention". None of the examples show that the peptides can "prevent" the disease from occurring because the peptides are not administered prior to the onset of the disease. Additionally, Cohen, Science vol. 262 p. 841 (1993) discloses that cancer vaccines are "highly experimental" (p. 843, second column, lines 4-5) and that "cancer vaccine efficacy... should be taken with a large chunk of salt" (page 843, first column, lines 9-10). Thus, the state of the art clearly discloses the unpredictability in the art of cancer vaccines and in view of lack of guidance in the specification to enable "prevention" or "vaccines", undue experimentation would be required by one skilled in the art to make and use the claimed invention.

8. Claims 15-18 and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. In claim 15, line 2, the terminology "derived from" renders the claim vague and indefinite. "Derived from" what part of gp100?
- b. In claim 17, line 3, "and" should be --or--.
- c. In claim 22, line 1, "a" should be deleted.
- d. In the last line of each of claims 23-26 "or" should be --and--.
- e. Claims 28-29 and 31 are dependent on non-elected claims.
- f. In claim 30, the host needs to be specified in the preamble of the claim.

#### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 15-16 and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Maresh et al DNA and Cell Biology vol. 13 p. 87 (2/94).

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This reference discloses the deduced amino acid sequence of ME-20(Fig. 2) and the expression of ME-20(p. 91-92). The amino acid sequence of ME-20 corresponds to gp100. It is inherent that the sequence produced by expression of cDNA corresponds to the deduced amino acid sequence.

11. Claims 15-16 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/21767.

The WO reference discloses a peptide beginning with KVPRN... on page 20. This sequence corresponds to a peptide derived from gp100 (specifically amino acids 25-53 of gp100).

#### *Conclusion*

12. PNAS, vol. 91 p. 3515 is not prior art because it was published on 4/26/94, which is after the filing date of the parent application. Seq. ID 27 and the peptides of claims 17 and 18 have priority to the parent application.
13. Claims 17-18 and 22-26 and 29-31 are free from the art of record because the prior art does not teach or suggest the claimed peptides or the use of the peptides in the treatment of melanomas.
14. No claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number

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is (703) 305-7866. The examiner can normally be reached on Monday-Thursday from 6:30am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703)308-2731. The FAX phone number for this Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sheela J. Huff  
October 24, 1996



TONI R. SCHEINER  
PRIMARY EXAMINER  
GROUP 1806